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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/338,221	06/22/1999	ELI PINES	22553/17	1129

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EXAMINER	
GUPTA, ANISH	

ART UNIT	PAPER NUMBER
1653	10

DATE MAILED: 04/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/338,221	PINES ET AL.	
	Examiner	Art Unit	
	Anish Gupta	1653	

-- The MAILING DATE of this communication appears on th cov r sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *29 January 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 18-34* is/are pending in the application.

4a) Of the above claim(s) *18-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The amendment filed 1-29-02 is acknowledged. Claims 1, 2 and 13 were amended. Claims 1-14 and 19-34 are pending in this application.

Election/Restriction

2. Applicant's election without traverse of Group I, claims 1-14, in Paper No. 9 is acknowledged. Claims 18-34 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected Group II and Group III.

3. This application contains claims 18-34 drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

4. The rejection of claims 1-14, rejected under 35 U.S.C. § 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim, is hereby withdrawn.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and

invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-11 and 13 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Schwarz et al. in view of Tripodi. for the reasons set forth in the previous office action and the reasons set forth below.

The claims are drawn to a therapeutic composition comprising fibrinogen.

Applicants argue that the reference of Schwarz et al. teach in an amount at least 70mg/ml. The instant application, however, provides that the therapeutically effective strength at fibrinogen concentration is only about 10mg/ml. Applicants make reference to the advantages of using the fibrinogen composition at such a low concentration. Applicants further assert that the secondary reference does not cure the shortcomings of Schwarz. In fact the reference teaches away from the claimed invention since the reference recommends the use of PEG-8000 instead of PEG 1000 as currently claimed.

Applicant's arguments filed 1-29-02 have been fully considered but they are not persuasive.

As stated in the previous office action, Schwarz et al. teach a tissue adhesive composition for wound closures that comprise fibrinogen that is capable of cross-linking with fibrin-γ-chains after 3 to 5 minutes of incubation (see claim 1) and the secondary reference provides motivation to

use bovine fibrinogen. Applicants have argued with respect to concentration. However, the claims read that "recovered fibrinogen is **capable** of polymerizing when provided in solution at said site at a concentration of about 10mg/ml thereof or less." Thus, the claims infer that the concentration can be at 10mg/ml or less but does not have to be used at this concentration. Further, the recited limitation can be seen as a functional limitation of the composition that is "capable" of polymerizing a low concentration. The reference discloses a fibrinogen composition that is useful in wound closure that is effective on contact with thrombin. The reference meets all of the structural limitation of the claimed composition. Since the reference teaches a composition with all of the structural limitations, such a composition would necessarily possess the functional limitations.

As for the arguments with regards to the use of PEG-1000, such a limitation renders the claim a product by process. The MPEP clearly states "The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." MPEP 2112.02. Here as stated above, the product is the same since the product comprises fibrinogen, is effective on contact with thrombin and is used for wound closures. Thus, the claims are "claim is unpatentable even though the prior product was made by a different process."

Rejection is maintained.

6. Claims 1-3, 7-11, and 13-14 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Stroetmann et al. ('650) or Stroetmann et al. ('655) in view of Tripodi et al. for the reasons set forth in the previous office action and the reasons set forth below.

7. Claims 1-3, 5, 7-11, and 13-14 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Stroetmann et al. ('650) or Stroetmann et al. ('655) in view of Tripodi et al. in further view of Farrell et al. for the reasons set forth in the previous office action and the reasons set forth below.

For both rejections, Applicants argue similar points and these have been addressed below.

The claims are drawn to a therapeutic composition comprising fibrinogen.

Applicants argue that the fibrinogen that is used in the Stroetmann et al. is from human plasma. This us unlike the claimed invention where non-human fibrinogen sources are used. Moreover, Stroetmann et al. also teach the use of fibrinogen n the concentration of about 50-80 mg/ml. The secondary reference of Tripodi and Farrell do not cure the deficiencies of the primary reference. Tripodi et al. teaches away from the claimed invention since the reference recommends the use of PEG-8000 instead of PEG 1000 as currently claimed. Farrell is a "technical paper merely documenting the investigation of the minimal concentration of ε-amino caproic acid in plasma required to induce total suppression of in-vitro fibrinogenolysis and fibrinolysis."

Applicant's arguments filed 1-29-02 have been fully considered but they are not persuasive.

In the previous office action, it was acknowledged that the primary reference taught the use of human plasma fibrinogen. However, the secondary reference, Tripodi et al., was cited to illustrate that bovine fibrinogen could be used instead of a human source. In their response, Applicants did not address why the secondary reference did not provide motivation to use bovine

fibrinogen as a source. Applicants have made arguments with regards to process of making. However, as stated above the MPEP clearly states "The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." MPEP 2112.02. Here as stated above, the product is the same since the product comprises fibrinogen, is effective on contact with thrombin and is used for wound closures. Thus, the claims are "claim is unpatentable even though the prior product was made by a different process."

It seems that applicants have also, with respect to Stroetmann et al., made some reference to concentration used. As stated above, the claims read that "recovered fibrinogen is **capable** of polymerizing when provided in solution at said site at a concentration of about 10mg/ml thereof or less." Thus, the claims infer that the concentration can be at 10mg/ml or less but does not have to be used at this concentration. Further, the recited limitation can be seen as a functional limitation of the composition that is "capable" of polymerizing at a low concentration. The reference discloses a fibrinogen composition that is useful in wound closure that is effective on contact with thrombin. The reference meets all of the structural limitation of the claimed composition. Since the reference teaches a composition with all of the structural limitations, such a composition would necessarily possess the functional limitations.

Finally, with respect to Farrell et al., Applicants have not provided any arguments as to why one would not be motivated use ϵ-amino-caproic acid in the plasma derivative to inhibit fibrinogenolysis. Applicants have only provided a brief description of the reference without any substantive arguments as to why the reference could not be applied.

Both rejections are maintained.

8. The rejection of claims 1-11 and 13-14 rejected under 35 U.S.C. 103(a) as being unpatentable over Stroetmann et al. ('650) or Stroetmann et al. ('655) in view of Tripodi et al., Farrell et al. and Miyano et al. is hereby withdrawn.

9. Claims 2 and 12 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Stroetmann et al. ('655) in view of Richter (abstract) and Tripode et al. for the reasons set forth in the previous office action and the reasons set forth below.

The claims are drawn to a therapeutic composition comprising fibrinogen.

Applicants argue similar points with respect to Stroetmann et al. and Tripode et al., which have been discussed supra. With respect to Richter et al. applicants state that Richter is merely directed to a preparation of rat fibrinogen and a comparison of the intermediate, as well as final products, of rat fibrinogen with those of human fibrinogen.

Applicant's arguments filed 1-29-02 have been fully considered but they are not persuasive.

Richter et al., was cited to show that the method used by Stroetmann et al. to isolate fibrinogen resulted in the presence of .01% or less plasminogen. Thus, since the method isolating the fibrinogen, in Stroetmann et al, from plasma results in the presence of plasminogen, at a level of less than 1%, the composition of Stroetmann et al. would contain plasminogen. Applicants have not addressed why the conclusion stated by Richter could not be applied to Stroetmann et al. with respect to plasminogen.

The rejection is maintained.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can normally be reached on (703)308-2923. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Anish Gupta

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